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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,426	12/30/2003	David J. Hansen	20020605.ORI	8112

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/748,426

Applicant(s)

HANSEN ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The amendments to the specification are acknowledged and accepted. The objections are withdrawn.

Claim Objections

2. The objections to claims 1 and 13 are acknowledged and accepted. The objections are withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5, 7, 9-12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frey et al. (US 4,860,750, hereinafter "Frey") in view of Rowley et al. (US 6,080,188, hereinafter "Rowley"). Frey discloses the essential features of the claimed invention including barbs (41a and 41b) on the bifurcated legs and shoulders (42a and 42b) in the insertion tube (30), interlocking first and second latches (Fig. 5) and the following:

6. In regards to claims 1 and 7, Frey discloses an implantable pulse generator (10), a device connector with a longitudinally extending bore (14), an electrical contact disposed within the connector (18) to cooperate with a conductive pin (25 and 24), a first and second side port in general alignment with the contact (Fig. 3), a first latch member adapted for insertion into the first port and having bifurcated legs (Fig. 4), and a second latch member (38) that is inserted through the second side port to spread the bifurcated legs and press the elastomeric tube (26) against the conductive pin (25 and 24) to hold the pin in place against the contact (18). Please note that examiner is interpreting the "pin" to comprise both elements 25 and 24.

7. In regards to claims 3 and 10, the first latch member comprises a flat head (45) with integral legs extending perpendicularly (40a and 40b).

8. In regards to claims 4 and 11, the second latch member comprises a flat head (unlabelled surface at far right of element 38 in figure 4a) and an integral tapered wedge extending perpendicularly (43).

9. In regards to claim 14, the contact, first latch, and second latch cooperate with a predetermined portion of the conductive pin (portion shown in element 18), defined by an international standard for medical leads (col. 4, line 65). Examiner is interpreting "unipolar" as an international standard.

10. Frey does not disclose an elastomeric tube, crosswise to the bore, and having a central lumen. Rowley teaches of providing an elastomeric tube (Fig. 11, element 118) for applying a tool-less frictional fixation means to a medical lead to avoid rough contact with the lead body, while still providing the contact force necessary to fix the lead in place. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Frey's invention with a crosswise tube made of an elastomer for applying a tool-less frictional fixation means to a medical lead to avoid rough contact with the lead body, while still providing the contact force necessary to fix the lead in place.

11. Additionally, claims 1-3, 5, 7 10, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowley in view of Frey. Rowley discloses the essential features of the claimed invention, including an IPG with a connector having an electrical contact (Fig. 6), a first and second side port (Fig. 2) in "general alignment" with the contact, an elastomeric tube oriented crosswise to the bore (118), a first latch member (112), and a second latch member inserted into the first member to force the legs apart (117 and col. 5, line 44). Furthermore, Rowley discloses a shoulder on the tube that receives barbs (114) of the first latch member (Fig. 11), a first latch member with a flat surface and legs extending perpendicularly (Fig. 11). Rowley does not disclose that the

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two members latch when squeezed together. Frey teaches of a locking mechanism that engages a lead by squeezing two members together to allow ease of lead engagement in slippery surgical environment. Therefore, it would be obvious to one having ordinary skill in the art at the time the invention was made to provide Rowley's invention with a squeeze engagement configuration to allow ease of lead engagement in a slippery surgical environment.

12. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frey in view of Rowley, as applied to claims 1 and 7 above, and further in view of Bradshaw (US 5,486,202 hereinafter "Bradshaw"). The modified invention of Frey discloses the essential features of the claimed invention except for an elastomeric tube that provides a fluid impervious seal when latched. Bradshaw teaches of providing an elastomeric seal (40) that provides a fluid impervious seal when latched to disrupt electrical continuity between the contact and the body fluid. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Frey's modified invention with an elastomeric seal that provides a fluid impervious seal when latched to disrupt electrical continuity between the contact and the body fluid.

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frey in view of Rowley, as applied to claim 12 above, and further in view of Bradshaw. The modified invention of Frey discloses the essential features of the claimed invention except for an elastomeric tube with flanges that provide a fluid impervious seal when latched. Bradshaw teaches of providing an elastomeric flange (40) that provides a fluid

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impervious seal when latched to disrupt electrical continuity between the contact and the body fluid. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Frey's invention with an elastomeric flange that provides a fluid impervious seal when latched to disrupt electrical continuity between the contact and the body fluid.

Response to Arguments

14. Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

15. In response to applicant's argument that the Frey and Rowley references are "significantly different", the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK



3/20/06


GEORGE R. EVANISKO
PRIMARY EXAMINER

3/20/06